

Remarks

Claims 1-3, 7-22, 24-41, 43-46, and 48-53 are pending. Claims 1-53 were pending and rejected by the Examiner. Claims 4-6, 23, 42 and 47 have been cancelled. Claims 1-3, 8, 10, 12, 16, 24-30, 33-37, 40, 41, 43, 44, and 50-52 have been amended to better represent the Applicants' invention. No new matter has been introduced. Reconsideration and allowance are respectfully requested.

Claim Rejections - 35 U.S.C 103

Claims 1 and 2 have been rejected under 35 U.S.C 103(a) over Knudson et al (US 6,636,767) in view of Li et al. (PTO-892 item U). Claims 1 and 2 have been amended. As amended, Applicants respectfully request reconsideration and allowance.

Claim 1 as amended now recites a method of treating snoring comprising: inserting an imaging device into the airway passage of a patient; monitoring, with the imaging device, the airway passage during sleep to identify at least one anatomical structure in the airway passage that vibrates during snoring; introducing, with an injection tool, at least one microstimulator in the proximity of the at least one anatomical structure identified, wherein the injection tool penetrates tissue in the proximity of the identified anatomical structure; energizing the microstimulator to deliver a test electrical stimulation to the anatomical structure to cause at least one muscle to contract and reduce the vibration of the anatomical structure, wherein the microstimulator is energized while held within the lumen of the injection tool; observing, with the imaging device, whether the test stimulation caused a decrease in vibration of the

anatomical structure; and releasing, if a decrease in vibration of the anatomical structure is observed, the microstimulator from the injection device into the anatomical structure.

Claim 1 is not obvious in light of the cited references. Claim 1 is directed to a method of monitoring the airway passage of the patient during sleep and determining the effective location that the stimulator should be implanted. The method further determines the efficacy of the location prior to releasing the stimulator into the site. Based on the present method, each patient would receive a customized treatment rather than a less precise, one-size-fits-all approach.

Knudson, however, fails to teach monitoring the airway passage before implanting the microstimulator, as required by amended claim 1. This failure is significant since the exact vibrating anatomical sites that contribute to snoring could be different among patients. For example, while one patient may only require only one stimulator in a specific location, the others may require a plurality to be implanted in different anatomical locations.

Knudson, on the other hand, treats snoring by an implant stimulating the muscles of one or more of the soft palate SP, tongue T and back of the throat.

Knudson specifically recites in column 4, lines 15-35:

"The implant 10, 10', 10" can be positioned and stimulated in a plurality of ways to alter the shape of the airway, to change the dynamic response of the airway tissues or a combination of both. The present invention permits the surgeon to apply stimulation to various muscles until the desired alteration in airway area and tone is achieved so that snoring inducing oscillation is abated at normal airflow. The individual electrodes 10, 10', 10" may be placed into the soft palate, tongue or throat muscles through small individual incisions closed by sutures which is much less traumatic than the gross anatomical destruction of

uvulopalatopharyngoplasty or the large surface area scarring proposed by Huang, et al.”

As disclosed in the cited passage above, Knudson implants the stimulators 10, 10', 10" into the soft palate, tongue or throat muscles. These stimulators are also implanted preemptively regardless of the effective target area that vibrates during sleep. Therefore, Knudson fails to teach Applicant's monitoring method as claimed.

The Examiner turns to the abstract in Li et al. to remedy deficiencies of Knudson. Li et al. teach analyzing collapse sites of pharynx and their anatomical causes during sleep in patients with obstructive sleep apnea. The analysis is based on endoscopically monitoring the pharynxes in patients. However, Li et al. do not teach or suggest a method of monitoring the airway passage of the patient to determine an effective location to release the microstimulator in order to reduce vibrations that cause snoring. Li et al. also fails to teach step (e) of the claim -- observing with the imaging device whether the test stimulation caused a decrease in vibration of the anatomical structure as required by the claim.

Neither Knudson et al. or Li et al. teach monitoring the airway passage in order to implant a microstimulator or observing, with the imaging device, whether the test stimulation caused a decrease in vibration of the anatomical structure.

To establish a *prima facie* case of obviousness . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations. (M.P.E.P 2143).

In the instant case, a *prima facie* case has not been established since the references by themselves or in combination fail to teach each and every limitation of Claim 1, as required by M.P.E.P 2143 cited above.

A *prima facie* case of obviousness also requires the articulation of an apparent reason as to why the skilled artisan would have combined the teachings of these references. See *KSR International v. Teleflex*, 2007 Lexis 4745 (April 30, 2007). No such reason has been articulated. To the contrary, the rejection appears to have been based on the very hindsight which the Supreme Court cautioned against in *KSR*.

Therefore, claim 1 is not obvious over Knudson et al. in view of Li et al.

Claim 2 depends upon claim 1 and thus is also not obvious over Knudson et al. in view of Li et al.

Claims 3-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al in view of Li et al. and Richmond et al. (USPN 6,240,316). Claims 3, 8, 10, 12, and 16 have been amended and claims 4-6 have been cancelled. As amended and cancelled, Applicants respectfully request reconsideration and allowance.

Claims 3 and 7-22 all depend upon claim 1 which, as explained above, is not obvious over Knudson et al in view of Li et al. None of the deficiencies in Knudson et al and Li et al., as noted above in connection with claim 1, are remedied by Richmond.

Claims 24, 26, and 28-39 were rejected as being unpatentable over Knudson et al in view of Li et al. and Richmond et al. Claims 24, 26, and 28-37

have been amended. As amended, Applicants respectfully request reconsideration and allowance.

Claims 24, 26, and 28-39 all depend upon claim 1 which, as explained above, is not obvious over Knudson et al in view of Li et al. None of the deficiencies in Knudson et al and Li et al., as noted above in connection with claim 1, are remedied by Richmond.

Claims 43-53 have been rejected under 35 U.S.C 103(a) over Pitts (US 20020048479) in view of Kallok (US 5,158,080). Claims 43, 44 and 50-52 have been amended and claim 47 has been cancelled. As amended and cancelled, Applicants respectfully request reconsideration and allowance.

Claims 43 and 53 have been amended to depend from claim 1. As explained above, claim 1 is patentable in view over Knudson et al. in view of Li et al. Neither Pitts nor Kallok remedy the deficiencies of Knudson and Li et al. Claims 43 and 53 are therefore also not obvious over Pitts in view of Kallok.

Claims 44-46 and 48-52 all depend upon claim 43 and thus are also patentable in view of Pitts and Kallok.

Claims 40 and 42 have been rejected under 35 U.S.C 103(a) over Richmond et al. Independent claim 40 has been amended to be similar to amended claim 1, and claim 42 has been cancelled. As amended and cancelled, Applicants respectfully request reconsideration and allowance.

Richmond et al. fail to teach a method of monitoring the airway passage of a patient in order to determine an effective location to implant a microstimulator in order to reduce vibrations that cause snoring. Richmond et al. also fail to teach

step (e) of claim 1 (step (f) in claim 40) which recites observing, with the imaging device, whether the test stimulation caused a decrease in vibration of the anatomical structure. Therefore, independent claim 40 is not obvious over Richmond et al.

Claim 41 has been rejected under 35 U.S.C 103(a) as being unpatentable over Richmond et al. as applied to claim 40 and further in view of Pitts. Claim 41 depends from Claim 40. Claim 40 is not obvious in view of Richmond et al. for the reasons stated above. Pitts does not remedy the deficiencies in Richmond et al. Claim 41 is therefore not obvious in view of Richmond et al. and Pitts.

Claim Rejections - 35 U.S.C 102

Claims 23, 25, 27, 33 and 35 have been rejected under 35 U.S.C 102(e) as being anticipated by Knudson et al. Claims 25, 27, 33 and 35 have been amended and Claim 23 has been cancelled. As amended and cancelled, Applicants respectfully request reconsideration and allowance.

Claims 25, 27, 33 and 35 have been amended to depend from amended claim 1. As explained above, Knudson et al. lacks elements of claim 1. Claims 25, 27, 33 and 35 are therefore also not anticipated by Knudson et al.

Claims 23 and 25 have been rejected under 35 U.S.C 102(b) as being anticipated by Pitts. Claim 25 has been amended and Claim 23 has been cancelled. As amended and cancelled, Applicants respectfully request reconsideration and allowance.

Claim 25 has been amended to depend from amended claim 1. As explained above, claim 1 is patentable in view over Knudson et al. in view of Li et

al. Pitts does not remedy the deficiencies of Knudson and Li et al. Claims 25 is therefore also not anticipated by Pitts.

Claims 23, 25, and 34-35 have been rejected under 35 U.S.C 102(b) as being anticipated by Richmond et al. Claims 25 and 34-35 have been amended and Claim 23 has been cancelled. As amended and cancelled, Applicants respectfully request reconsideration and allowance.

Claims 25 and 34-35 have been amended to depend upon claim 1. As explained above, Knudson et al. and Li et al. lack elements in claim 1. Richmond et al. does not remedy these deficiencies. Claims 25 and 34-35 are therefore also not anticipated by Richmond et al.

Conclusion

Applicants respectfully submit that the above amendments place this application in condition for allowance, which Applicants respectfully solicit.

A petition for a three-month extension of time under 37 C.F.C. 1.136 is being filed contemporaneously herewith. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-087.

Respectfully submitted,
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